K 013818
page 1 of 4

DEC 0 5 2001

AUTOGENESIS

8700 Old Harford Rd
Baltimore, MD 21234
Phone 410 665 2017, Fax 410 665 1616

Section I: Premarket 510(k) Device Modification Summary

As required by section 807.92(c).

Applicant and Company's Name:	Autogenesis™ Inc.
Address:	Autogenesis Inc. 8700 Old Harford Rd Baltimore, MD 21234
Contact Person:	James Edwards, President of Autogenesis Inc.
Date Summary was Prepared:	April 1, 2001
Trade or Proprietary Name:	Autogenesis™ Automator
Common or Usual Name:	Automatic distraction component for external fixation devices.
Classification Name:	Orthopedic Device: (Component for) smooth or threaded metallic bone fixation fastener.

Predicate Device to which Equivalence is Claimed:

The Autogenesis™ Automator is a modified version of Automator 2000, also manufactured by Autogenesis™ Inc. The Automator is substantially equivalent in terms of safety and effectiveness to Automator 2000. The predicate device received clearance May 20, 1998 under 510(k) Premarket Notification Number K981423.

Device Description:

Distraction osteogenesis is the process by which our bodies are able to "grow" bone and soft tissues at a fracture site if the bone fragments are gradually separated at a rate approximating 1 mm per day. The Automator is a simple battery powered, motorized device used to accomplish precision distraction for the purpose of bone and soft tissue (re)generation. The programmable device is used as a component on commonly available external fixation frames. Specifically, the device accomplishes micro-adjustments of a telescoping rod, which, in turn, positions the external frames, and bone segments to which the frames are attached.

Adjustment of external frames for bone positioning is presently performed with Automator 2000 or manual adjustment techniques. The Automator is a modified version of the Automator 2000. The device is physically smaller in size and weight while retaining the same basic design and safety features of Automator 2000. Additionally, the Automator's user interface has been enhanced to include an LCD and two control buttons. The upgraded interface makes additional rate settings available to the user. A programming option of cyclic motion was added to aid with pseudoarthrosis (non-union) healing.

Modifications to the predicate device include the devices housing, gearing, circuitry, software, and battery supply. The mechanical design of the Automator is very similar to the design of Automator 2000. The design modifications mostly involve miniaturization of Automator 2000. For further description of the Automator please see the body of this 510(k) application.

Indications for use:

The Autogenesis™ Automator™, in conjunction with standard, commercially available circular and unilateral fixation devices, may be used to perform controlled adjustment and positioning of long bones. The Automator may replace the Automator 2000 or manual adjustment devices where they are traditionally applied. Indications for such use include the following:

- the correction of bony or soft tissue deformities,
- limb lengthening by epiphayseal and metaphyseal distraction,
- bone thickening and/or lengthening of amputated stumps,
- fracture fixation (open or closed),
- pseudoarthrosis or non-union of long bones,
- correction of segmental bony or soft tissue defects.

Summary of How Technical Characteristics of the Automator Compare to the Automator 2000:

Power: The Automator requires less power than Automator 2000. Hence, the device can run equally long as its predecessor on battery cells with less capacity. The Automator is powered by two 1/2AA lithium cells rather two AA lithium cells. Like Automator 2000, the Automator is expected to run in its most common distraction mode 6 months on its internal battery.

Precision: Like Automator 2000, the Automator makes use of a robust DC motor and breaking system that is able to maintain impressive accuracy. As a result of the motor choice, the software algorithm for controlling the motor adjustments may demand a high level of precision for the telescoping rod adjustment. Automator 2000 maintains accuracy within $1/64^{th}$ mm. This compares to Automator 2000's accuracy of 1/72mm, and the earlier CF Automator design of 1/32mm.

Motor Control: The Automator uses the same DC Motor with a gear reduction ratio of 5752:1 as Automator 2000. The gearing results in a high torque and slow RPM output.

A minor modification in motor timing allows the new Automator to make adjustments in 1/384th mm increments, slightly smaller than Automator 2000's 1/360th mm increments.

Housing & Enclosure: Like Automator 2000, the Automator has the control circuitry, drive components, and battery contained in a single housing. The new design is even more compact and light weight than its predecessor. The housing will still be machined from aluminum. The machined aluminum housing is a robust design that comfortably accommodates the axial force and impact load requirements of the device.

The new product will not require a cap that covers switches used to program the device. The Automator will be programmed using two control buttons on the front of the device, with visual feedback from an LCD. Hence, the housing will be very similar, though simplified relative to the housing of Automator 2000.

Circuitry and Software/ Safety Features: The Automator's design requires a smaller circuit board, relative to the circuit board in Automator 2000. Certain software modifications were required to allow for component changes required by the miniaturization. Additional modifications to code were required for user interface changes and additional programming selections. User interface and miniaturization aside, the new Automator uses the same self diagnostic and circuitry controls as its predecessor. These controls assure that the telescoping rod is adjusted only the *amount* it is intended to, and only *when* it is intended.

The Automator has an expanded selection of programmable settings relative to Automator 2000. Instead of 7 rate settings from which to choose, the user now has 13 settings. The user may also now program the total distraction they wish the Automator to perform before providing an audible and visual alarm. Furthermore, the user may program the Automator to perform tiny motions forwards and backwards without net movement (cyclical motion). This cyclical motion functionality is available in manual devices but had not been incorporated into the design of Automator 2000. With Automator 2000 the user was required to perform cyclical motion by manually adjusting the telescoping rod.

Regarding motor control, the Automator and Automator 2000 have virtually identical software and circuitry safety features. Both systems have been designed to use the *final* drive gear as an encoder to verify the position of the telescoping rod. Each system will enter an error mode and produce audio and visual alarms if the encoder does not verify that distraction is progressing within tolerable accuracy. Both systems check current on the motor circuit to verify the motor runs only when it is supposed to, and furthermore, check current during motor pulses to verify that current is not higher than expected. Both motor circuits have switches that remain open between motor pulses to prevent the motor from receiving current. Both systems use a watch-dog circuit to confirm normal software operation nearly continuously. Both systems have redundant audio and visual alarms. Furthermore, both units use the same design telescoping rod, which may be used to make manual lengthening adjustments at any time.

Performance Characteristics for Load on Telescoping Rod: The Automator and Automator 2000 are both designed to handle the same axial load. Like Automator 2000, the Automator is designed to alarm when resistance approximates an axial load of 250

lbs. Additionally, both Automator designs can accommodate impact loads of 50 lbs. on the telescoping rod.

In summary, modifications made to the design of Automator 2000 have succeeded in making the device smaller and lighter. The user also is provided with a more complete range of programming options. The Automator continues to use the same safety controls that are responsible for Automator 2000's record of safe and effective use.

Non-Clinical Performance Testing:

The Automator was designed in accordance to the design control guidance for medical device manufacturers published March 17, 1997. As a part of the verification exercises performed during the product modification and design process, multiple tests were conducted. Testing was performed to verify the following: 1. The motor selected would generate sufficient torque. 2. The motor would not require excessive power. 3. The motor output speed would be slow enough to control with the processor, but fast enough to be energy efficient. 4. Two ½ AA lithium batteries would be adequate to power the device, 5. The software algorithm used to control the motor would reliably assure accuracy to $1/64^{th}$ mm. 6. All mechanical components selected would be adequate to sustain specified levels of axial and impact loading. 7. Integration, and verification of all functions, error modes, and self diagnostic procedures in the product's software and hardware had been accomplished

Furthermore a traceability matrix was maintained to assure that all design input has been accomplished by the design of the device. All testing confirmed that the design for the Automator was safe and effective, and that the predetermined design input was properly implemented.

Further design validation was performed through dynamic testing of the device under variable loads, temperatures, and battery voltages. Life testing of the device further confirmed the battery life expectancy and documented continuous error free operation.

Design controls for the device modifications were implemented at the initiation of the project. Hence, the design was subject to thorough review during the entire modification/design process. Autogenesis retains clear documentation of input requirements, design output, design reviews, verification activities, and validation activities

In summary, the Automator was designed to be as safe and effective as Autogenesis' Automator 2000. Design verification and validation activities have demonstrated that the design requirements have been fully and properly implemented. In light of the design controls maintained by Autogenesis, and in light of the studies and testing performed on the Automator that confirm its safety and effectiveness, the Automator has been demonstrated to be substantially equivalent in safety and effectiveness to the Automator 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Edwards
President
Autogenesis, Inc.
8700 Old Harford Road
Baltimore, Maryland 21234

DEC 0 5 2001

Re: K013818
Trade/Device Name: Autogenesis™ Automator
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JEC
Dated: November 15, 2001
Received: November 16, 2001

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013818

Device Name: Autogenesis Automator

Indications For Use:

The Autogenesis™ Automator™, in conjunction with standard, commercially available circular and unilateral fixation devices, may be used to perform compression or distraction on long bones. The Automator™ may replace Automator™ 2000 or manual distraction and compression devices where they are traditionally applied. Indications for such use include the following:

- the correction of bony or soft tissue deformities,
- limb lengthening by epiphayseal and metaphyseal distraction,
- bone thickening and/or lengthening of amputated stumps,
- fracture fixation (open or closed),
- pseudoarthrosis or non-union of long bones,
- correction of segmental bony or soft tissue defects.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013818

Prescription Use [redacted] OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)